AKZO NOBEL FUNCTIONAL CHEMICALS LLC

June 7, 2002

Oscar Hernandez, Director
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116
Attn: Right-To-Know

Re: Response to EPA Comments on HPV Test Plan for Trixylenyl Phosphate

Dear Mr. Hernandez:

Akzo Nobel Functional Chemicals LLC is pleased to respond to your letter of May 9, 2002, and to the comments on our proposed Test Plan that you sent on behalf of the Office of Pollution Prevention and Toxics (OPPT). We are in agreement with the OPPT comments and have prepared a revised Trixylenyl Phosphate Test Plan, a copy of which accompanies this letter.

Our company is committed to the principles of the October 14, 1999 Letter, which emphasizes the analysis and use of existing, scientifically adequate data wherever possible, rather than utilizing a box-checking approach in fulfilling HPV requirements. To be sure that all available Trixylenyl Phosphate data was being examined, we searched company files for reports and other documents, searched several electronic databases for published information on the product, and asked trade associations to conduct searches of their respective records. All of the reports, publications, correspondence, and other documents pertaining to Trixylenyl Phosphate were carefully examined and where possible, their data were included in the robust summaries. This effort has significantly reduced our testing requirements.

The October 14, 1999 Letter also emphasizes the need to minimize animal usage through the examination of several endpoints in a single test. Akzo Nobel Functional Chemical strongly supports this policy and has proposed in its Test Plan the use of the OECD Guideline 422 to measure subchronic toxicity, reproductive toxicity, and developmental toxicity in a single test, rather than conduct three separate tests. Principle number five of the Letter will be adhered to, and the needed genetic toxicity test will utilize an in vitro cell system, rather than live animals.

Many of the Agency's comments pertain to the identity of the test substance. In essentially all of the referenced studies in the Robust Summaries, the test substance consisted of the commercial product, which is sold under several product names. It is important to recognize that Trixylenyl Phosphate is not a single chemical entity, but consists of over 50 different components, many of which are structural isomers. The separation and chemical characterization of a mixture consisting of dozens of isomers is exceptionally difficult. For this reason, in many studies, only a partial analysis of the test substance was conducted. However, since the commercial product was evaluated in these tests, the results provide a valid assessment of the aquatic and mammalian toxicity of the product.

Akzo Nobel Functional Chemicals LLC has committed to conduct a biodegradation test, in addition to the photodegradation and stability in water tests, and fugacity modeling, which were proposed in the original Test Plan. In the Ecotoxicity area, EPA has rejected the existing acute fish toxicity test because the concentrations of the test substance were not measured. A new acute fish toxicity test will be conducted, as now shown in the revised Test Plan. We had previously agreed to conduct an acute daphnid test and an algal toxicity test, and these tests remain in our revised Test Plan.

With regard to the genetic toxicity testing, we believe the Ames Test conducted in 1984 properly evaluated the test substance up to its limit of solubility, and this satisfies the gene mutation endpoint. Akzo Nobel Functional Chemicals proposes to conduct an in vitro test for induction of chromosomal aberrations, such as the Chinese Hamster Ovary Cell Test.

Akzo Nobel Functional Chemicals is committed to obtaining as much information as possible from a single animal test so as to minimize the use of laboratory animals. Thus, to address the repeated dose, reproductive, and developmental toxicity endpoints, we will conduct OECD 422, the rodent screen, which evaluates all three endpoints in a single test.

We appreciate EPA's guidance and testing recommendations. We believe the revised Test Plan now includes all of the tests required to measure the SIDS endpoints while minimizing the use of laboratory animals.

Sincerely yours,

William F. Gentit
Manager, Regulatory Affairs

Last revised June 7, 2002